Amendments to the Specification

Please insert the following new paragraph after page 7, line 5 (i.e. between original paragraphs 21 and 22) of the specification:

D1

Fig. 3a is a side elevation showing a stent disposed within the outer assembly of Fig. 3.

Please replace paragraph 39 beginning on page 13, line 16 of the specification with the following amended paragraph:

[039] FIGS. 3-3a and 4a-4c show the outer and inner assemblies 105 and 104, respectively, of an exemplary embodiment of an apparatus 100 of this invention. The outer assembly 105 has been described in U.S. patent application Ser. No. 09/569,445, which is incorporated by reference herein in its entirety. A brief review of this outer assembly 105 will be made herein for clarity. The outer assembly 105, as shown in FIG. 3, may have a non-braided clear and/or translucent distal region 105a welded at area 115 to a braided opaque proximal region 105c at a transitional region 105b for added kink resistance and improved force transmission. The distal region 105a may be 8 French, or any other dimension as long as it does not hinder movement of a stent 102 within. The clear distal region 105a partially covers the stent 102 during insertion of the delivery system 101 into a patient's body 190. As shown in Fig. 3a, region 105a may have a length that substantially coincides with a constrained length of stent 102 within the outer tubular structure. Also, the outer assembly 105 may be any material that is naturally flexible and biocompatible, such as polyether block amide (Pebax), other low density polymers, or other suitable materials. The clear and/or translucent region 105a allows a health care worker to observe the relative movement of the stent 102 during deployment such that the stent is deployed in a suitable area, and the proximal end of the stent is visible to the health care worker as the proximal end passes within the clear region 105a before stent release. The distal end of the assemblies 104, 105 and stent deployment may be viewed by any suitable known method, including, for example, an endoscope with camera system, or through fluoroscopy. The proximal region 105c extends a substantial distance along the length of the delivery system 101, and is constructed of relatively stiff material, such as 72D Pebax, to maintain the strength of the delivery system 101. The transitional region 105b is a point of adhesion between the flexible, clear and/or translucent material in the distal region 105a and the relatively stiff, strong material in the proximal region 105c.

D2

Please replace the paragraph 40 beginning on page 14, line 17 of the specification with the following amended paragraph:

[040] Because the distal region 105a in the exterior tube assembly 105 may not be braid reinforced and typically is thin walled, typically 0.006" - 0.008" width walls, for flexibility, it may be likely to kink around a bend unless internally supported. Thus, the inner assembly 104 may include an inner elongated structure 104b, which may be constructed of polyetheretherketone (PEEK), having one or more jackets 104a, which may be made of Pellethane, along its length to minimize friction when the one or more

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP
1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

jackets 104a contact the interior surface of the outer assembly 105. Furthermore, a jacket 104a may provide interior support to the distal exterior tube region 105a. As shown in Figs. 4a-4c, the layer of Pellethane typically is on a shortened jacket 104a of a conventional material, such as PEEK, used as a material for the inner elongated structure 104b, which will be described as a tube in the illustrated embodiments. This jacket 104a is of sufficient length to support the non-braided, clear and/or translucent portion of the exterior tube 105a during, for example, reconstrainment around a curve. The jacket 104a typically is longer than the longest constrained length of the stent 102 to provide support for the stent 102. The combination of the inner assembly 104, having a jacket 104a with a layer of pellethane thereon, with the outer assembly 105, results in an endoscopic delivery system with excellent force transmission, a flexible stent region, and low requisite deployment/reconstrainment forces in tortuous anatomies.

Please replace the paragraph 42 beginning on page 15, line 20 of the specification with the following amended paragraph:

[042] The distal jacket 104a may be thermally attached proximal to the distal portion of the interior tube 104b. This jacket 104a may be a length that would support a constrained length of the stent 102, which typically is longer than its unconstrained length. A typical length for the jacket 104a may be approximately 130 mm. However, the length of the jacket 104a may be changed to accommodate stents 102 of different lengths. More particularly, the length of the jacket 104a may be that of the longest constrained stent length in order to provide internal support to the exterior tube assembly 105 until the point where the stent 102 is fully deployed into the anatomical structure 191. The proximal end of the stent 102 may be in communication with a holding cup 133 that holds the proximal end of the stent 102 and a holding sleeve 104c that is attached near the distal end of the inner assembly 104. The holding sleeve 104c may be an opaque sheet of plastic, such as Tecothane, for example, in a distinct color, such as red, for example, that holds the proximal end of the stent 102 and also serves as a visual indicator to a health care worker of the proximal end of the stent 102. The holding sleeve 104c may accommodate the stent 102 by friction, such as by laser cutting polymer from wire to create bare stent ends, and leaving silicone ribs on the backside of the wire, thus providing a high friction surface that comes in contact with the holding sleeve 104c. Additionally, during deployment, visual signal bands 131 that may be adjacent the holding sleeve 104c, and which may be radiopaque such as, for example, tantalum or platinum, may become visible through a fluoroscope through the clear and/or translucent portion of the exterior tube 105a, such that a health care worker would be signaled that the stent 102 is close to being deployed, thus if reconstrainment is necessary to re-position the stent 102, it would be time to do so. The stent 102 is free to move independently of the outer assembly 105 as directed by the inner assembly 104. As discussed above, to activate deployment of the stent 102, the outer assembly 105 typically is retracted proximally which moves the non-braided region 105a over the inner member jacket 104a. During reconstrainment of the stent 102, the inner assembly 104 may be pulled proximally while the exterior assembly 105 remains stationary. The low friction response of the jacket 104a with the interior lining of the outer assembly 105 typically results in less resistance than conventional stent deployment assemblies because there is a limited area of contact between the two assemblies. In an

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

exemplary embodiment, Pellethane tubing is used as the jacket 104a material and PTFE is used as the interior surface lining of the exterior assembly 105. Alternatively or additionally, the surface of the jacket 104a may be lubricated with a suitable lubricant such as MDX silicone to further decrease frictional forces opposing relative movement between the two assemblies. Other materials, besides Pellethane, also may be used for the jacket 104a as long as the materials exhibit relatively low frictional forces when in contact with the interior surface of the outer assembly 105. Such alternative materials for the jacket 104a may include low-density polyethylene.

Please replace the paragraph 43 beginning on page 17, line 14 of the specification with the following amended paragraph:

[043] FIGS. 5a and 5b show exemplary embodiments of the relationship between different components of a stent delivery device 101, including the stent 102, outer assembly 105, and inner assembly 104. As shown in these figures, an outer assembly 105, including a clear and/or translucent outer portion 105a, a transition region 105b, and a opaque braided region 105c, surrounds an inner assembly 104, including multiple Pellethane jackets 104a along an interior tube 104b. A holding sleeve 104c assists in holding and identifying the proximal end of a stent 102. At the distal end of the stent 102 is a marker band 131 that marks the front edge of the stent 102, thereby assisting in proper stent position during deployment. The marker band 131 may be radiopaque to be visible under fluroscopy. The lead point 117 is positioned distal to the marker band 131. The braid 139 in the outer assembly 105 may extend across the opaque region 105c and the transition region 105b, thereby partially covering the stent 102 held within the outer assembly 105. Part of the stent 102, however, may be visible through the clear and/or translucent region 105a. As stated above, during stent 102 deployment, when the marker band 131 adjacent the holding sleeve 104c is visible through the clear region 105a under fluoroscopy, a health care worker is signaled that the stent 102 is nearly completely deployed and, thus, any reconstrainment to re-position the stent 102 within the anatomical structure 191, if needed, should be initiated. Otherwise, the stent 102 will be completely deployed into the anatomical structure 191 and released from the delivery system 101.

Please replace the paragraph 45 beginning on page 19, line 7 of the specification with the following amended paragraph:

[045] Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. For example, the sequential increase in the durometer measure of subsequent contact areas of Figs. 6a-6c may occur at every other contact area, or other such trend, as long as there is an increase in flexibility from a proximal region to a distal region of the inner assembly 104. Also, there may be more than one distinct jacket layer 104a of Pellethane used in the illustrated embodiment depicted in Figs. 4a-4c, or stated differently, each of the jacket layers 104a1, 104a2, and 104a3 in Figs. 6a-6c may be Pellethane. More than or less than three jacket layers are possible in the illustrated embodiment depicted in Figs. 6a-6c. Furthermore, the length of the clear and/or translucent region 105a may be changed to suit the preference of health care workers

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

D6

so that either more or less of the constrained length of the stent 102 may be visible during deployment/reconstrainment. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com